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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,665	10/14/2003	Judith A. Varner	021935-000130US	5650

20350 7590 01/29/2007

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EXAMINER	
REDDIG, PETER J	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,665	VARNER, JUDITH A.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,9-12,15,19,20,55-72,75,80-95 and 97-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,4,5,9-12,15,19 and 20* is/are allowed.

6)☒ Claim(s) *55-72,75,80-95 and 97-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed December 6, 2006 in response to the Office Action of September 6, 2006 is acknowledged and has been entered. Previously pending claims 3 and 96 have been cancelled, and claims 1, 2, 55, 57, 95, and 114 have been amended.

2. Claims 1, 2, 4, 5, 9-12, 15, 19, 20, 55-72, 75, 80-95, and 97-120 are currently being examined.

3 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following rejections are being maintained:

Claim Rejections - 35 USC 112

5. Claims 118-120 remain rejected under 35 USC 112, second paragraph for the reasons previously set forth in the paper mailed September 6, 2006, section 7, pages 3-4. Applicant argues that those of skill in the art would understand what is meant by the phrase "chimeric antibody" when read in the light of the specification. Applicants argue that the phrase "chimeric antibody" is commonly used in the art to describe an antibody having a protein sequence in the variable region from one species, usually a mouse, in approximately 33 %, and a protein sequence in the constant region from another species, usually a human in approximately 67 %. and cites examples of chimeric antibodies.

Applicant's arguments have been carefully considered, but have not been found persuasive and the rejection is maintained because, although the phrase "chimeric antibody" is commonly used as described above, applicants are arguing limitations not found in the claims. Neither the specification nor the claims as written limit a "chimeric antibody" to an antibody

having a protein sequence in the variable region from one species, usually a mouse, in approximately 33 %, and a protein sequence in the constant region from another species, usually a human in approximately 67 %. Thus, without explicit definition of the chimeric antibody in the specification encompassed by the claims, the metes and bounds of the claim protection sought cannot be determined, because the term chimera is generic to a class of antibodies which are products of genetic shuffling of antibody domains and other active proteins.

6. Claims 55-72, 75, 89-95, and 97-120 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed September 6, 2006, section 9, pages 7-11.

Applicant argues that the claims are not limited to a method for reducing or inhibiting angiogenesis using humanized versions of antibodies and that the claims are not directed to methods for reducing or inhibiting angiogenesis while also inhibiting HAMA or immunogenic reactions so that the antibodies are clinically preferable. Applicant argues that the specification provides support for the use of different types of $\alpha 5\beta 1$ antibodies is examples 2-4. Applicant argues that the Action may be correct in that murine antibodies will have an immunogenic response, but this is a possibility known to the skilled person and so raises no issue of undue experimentation in relation to the claimed invention. Applicant argues that chimeric antibodies will have less immunogenic response, humanized antibodies even less and fully human antibodies even less. Applicant argues that that all $\alpha 5\beta 1$ antibodies (murine, chimeric, humanized, etc.) will reduce or inhibit angiogenesis in an individual, as the claims recite. Applicant argues that although some $\alpha 5\beta 1$ antibodies may be better clinically than others, this is beyond the scope of the claimed invention.

Applicant's arguments have been carefully considered, but have not been found persuasive and the rejection is maintained because the well known immune response to murine antibodies, encompassed within the claims as currently constituted, used in human patients makes it not possible to reliably predict that a completely murine antibody to $\alpha 5\beta 1$ would successfully treat a human tumor or a pathological condition associated with the eye in a human. A review of examples 2-4 did not show support for the use of murine antibodies for treatment of humans, but only for the use of murine antibodies in mouse models of angiogenesis/tumorigenesis.

7. All other objections and rejections recited in Office Action of September 6, 2006 are withdrawn.

8. Claims 55-72, 75, 80-95, and 97-120 are rejected.

9. Claims 1, 2, 4, 5, 9-12, 15, 19, and 20 appear allowable in their current form.

10. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application

which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

11. Applicant's amendments necessitated the new grounds of rejection/objection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0890. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

SUSAN UNGAR, PH.D
PRIMARY EXAMINER